



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington DC 20204

FEB 13 1998

Dr. J. N. Mutz
Monsanto Company
700 Chesterfield Parkway North
St. Louis, MO 63198

Dear Dr. Mutz:

This is in regard to your genetically modified Roundup Ready corn line GA21 about which you initiated consultations with the Agency on August 20, 1997. According to Monsanto, the Roundup Ready corn line GA21 has been modified to be Roundup (N-phosphonomethyl-glycine) resistant.

As part of bringing your consultation with FDA regard this product to closure, you submitted a summary of your safety and nutritional assessment of the Roundup Ready corn line GA21 on August 20, 1997. These communications informed FDA of the steps taken by Monsanto to ensure that this product complies with those legal and regulatory requirements that fall within FDA's jurisdiction. Based on the safety and nutritional assessment you have conducted, it is our understanding that Monsanto has concluded that the Roundup Ready corn line GA21 is not materially different in composition, safety, or other relevant parameters from corn currently on the market, and that it does not raise issues that would require premarket review or approval of FDA. All materials relevant to this consultation have been placed in a file that has been designated BNF 000051 and will be maintained by the Office of Premarket Approval.

Based on the information Monsanto has presented to FDA, we have no further questions concerning the Roundup Ready corn line GA21 at this time. However, as you are aware, it is Monsanto's continued responsibility to ensure that foods the firm markets are safe, wholesome, and in compliance with all applicable legal and regulatory requirements.

Sincerely yours,

Alan M. Rulis, Ph. D.
Director
Office of Premarket Approval
Center for Food Safety
and Applied Nutrition